

U.S. Patent Application No. 10/628,322
Amendment dated November 19, 2004
Reply to Office Action of August 23, 2004

REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

Claims 1, 4, 7, and 9-19 are pending in the application. Claim 8 has been canceled, and claims 2, 3, 5, and 6 had been canceled previously. The amendment to the claims further defines what the applicants regard as the invention. Full support for the amendment can be found throughout the present application and the claims as originally filed. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

At page 2 of the Office Action, the Examiner rejects claims 1, 4, 7, 8, 10, and 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,225,404. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims and claims 1-26 of the reference are directed at treating colon cancer. For the following reasons, this rejection is respectfully traversed.

The applicants do not agree with the rejection imposed by the Examiner. First, the '404 patent is not owned entirely by the same assignee as the present application. Further, the claims of U.S. Patent No. 5,225,404 specifically relate to treating malignant colon or colorectal cancer in mammals using certain camptothecin compounds. In particular, this patent relates to the treatment of colon tumors using 9-amino-20(S) or (RS) CPT; 10, 11-methylenedioxy-20 (S) or (RS)-CPT or a sodium salt thereof. Also, the claims of the '404 patent as well as the specification do not show dosage amounts of lower than 1.5 mg/kg/day. Also, claim 1 no longer includes the specific compounds set forth in the claims of the '404 patent. Therefore, there is no overlap nor any obvious overlap between the claims of the '404 patent and the claims pending in the present application.

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Clearly, the present claims are patentably distinct from the '404 patent. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Furthermore, the Examiner should note that the same rejection was issued in one of the related cases (U.S. Patent No. 6,624,170 B2). The Examiner in the related case found the arguments set forth above convincing to overcome the obviousness-type double patenting rejection. Accordingly, for the reasons set forth above, this rejection should be withdrawn.

At page 3 of the Office Action, the Examiner rejects claims 1, 4, and 7-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,552,154. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims and claims 1-6 of the reference are directed at treating breast cancer. For the following reasons, this rejection is respectfully traversed.

The applicants do not agree with the rejection imposed by the Examiner. Claim 1 of the present application specifically recites, in part, a method of treating a malignant tumor in a mammal comprising administering orally to the mammal in need of such treatment an effective amount of a water-insoluble camptothecin compound with a closed-lactone ring. In contrast, the claims of the '154 patent specifically recite transdermal administration of the camptothecin compound. The two routes of administration are quite different and unobvious from each other. Therefore, there is no overlap nor any obvious overlap between the claims of the '154 patent and the claims pending in the present application. Clearly, the present claims are patentably distinct from the claims of the '154 patent. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Accordingly, for the reasons set forth above, this rejection should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 1, 4, and 7-19 under the

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judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,652,244. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims and claims 1-8 of the reference are directed at treating a malignant carcinoma or osteosarcoma. For the following reasons, this rejection is respectfully traversed.

The applicants do not completely agree with the rejection imposed by the Examiner. However, in order to further the prosecution of this application, a Terminal Disclaimer is submitted with the response to the Office Action, wherein the assignee agrees that any patent issuing from the present application will expire on the same day as the expiration date of U.S. Patent No. 5,652,244, except for the exceptions set forth within the disclaimer. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Accordingly, this rejection should be withdrawn.

Also at page 5 of the Office Action, the Examiner rejects claims 1, 4, 7, 8, 10, and 12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-27 of U.S. Patent No. 5,889,017. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims are directed at treating a malignant tumor, while claims 1-27 of the '017 patent are directed at treating lung cancer or melanoma cancer by oral or intramuscular administration. For the following reasons, this rejection is respectfully traversed.

The applicants do not completely agree with the rejection imposed by the Examiner. However, in order to further the prosecution of this application, a Terminal Disclaimer is submitted with the response to the Office Action, wherein the assignee agrees that any patent issuing from the present application will expire on the same date as the expiration date of U.S. Patent No. 5,889,017,

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except for the exceptions set forth within the disclaimer. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Accordingly, this rejection should be withdrawn.

At page 6 of the Office Action, the Examiner rejects claims 1, 4, and 7-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,166,029. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims are directed at treating a malignant tumor, while claims 1-10 are directed at treating colon cancer by intramuscular or oral administration. For the following reasons, this rejection is respectfully traversed.

The applicants do not completely agree with the rejection imposed by the Examiner. However, in order to further the prosecution of this application, a Terminal Disclaimer is submitted with the response to the Office Action, wherein the assignee agrees that any patent issuing from the present application will expire on the same date as the expiration date of U.S. Patent No. 6,166,029, except for the exceptions set forth within the disclaimer. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Accordingly, this rejection should be withdrawn.

At page 7 of the Office Action, the Examiner rejects claims 1, 4, and 7-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,342,506 B1. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims are directed at treating a malignant tumor by oral administration, while claims 1-13 are directed at treating breast cancer by oral administration. For the following reasons, this

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rejection is respectfully traversed.

The applicants do not completely agree with the rejection imposed by the Examiner. However, in order to further the prosecution of this application, a Terminal Disclaimer is submitted with the response to the Office Action, wherein the assignee agrees that any patent issuing from the present application will expire on the same day as the expiration date of U.S. Patent No. 6,342,506 B1, except for the exceptions set forth within the disclaimer. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Accordingly, this rejection should be withdrawn.

At page 8 of the Office Action, the Examiner rejects claims 1, 4, and 7-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,624,170 B2. Further, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from one another because the instant claims and claims 1-15 of the '170 patent are directed at treating a malignant tumor by oral administration. For the following reasons, this rejection is respectfully traversed.

The applicants do not agree with the rejection imposed by the Examiner. Claim 1 of the present application specifically recites, in part, a method of treating a malignant tumor in a mammal comprising administering orally to the mammal in need of such treatment an effective amount of a water-insoluble camptothecin compound with a closed-lactone ring. In contrast, the claims of the '170 patent specifically recite that the water-insoluble compound with a closed-lactone ring is administered subcutaneously to the mammal in need of such treatment in an effective amount. The two administration routes are very different and unobvious from each other. Therefore, there is no overlap nor any obvious overlap between the claims of the '170 patent and the claims pending in the present application. Clearly, the present claims are

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patentably distinct from the '170 patent. With respect to claim 8, this claim has been canceled. Therefore, the rejection of claim 8 is moot. Accordingly, for the reasons set forth above, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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